The Secondary Use of Paediatric Data Under GDPR

Altavilla, Annagrazia ; Herveg, Jean; Giannuzzi, Viviana ; Landi, Annalisa ; Ceci, Adriana

Published in:
European Pharmaceutical Law Review

Publication date:
2019

Document Version
Publisher's PDF, also known as Version of record

The Secondary Use of Paediatric Data Under GDPR: Looking for New Safeguards for Research

*Annagrazia Altavilla, Jean Herveg, Viviana Giannuzzi, Annalisa Landi and Adriana Ceci**

Secondary use of personal data is particularly challenging for research, especially in paediatrics. The new EU General Data Protection Regulation (GDPR) enables a new legal framework for the data protection and personal data processing. This article analyses the GDPR provisions with the aim to verify if paediatric peculiarities are taken into account in the new framework and if GDPR provides adequate and clear rules to favour the secondary use of paediatric data for research purpose in international contexts. The analysis points out the lack of specific provisions covering paediatric peculiarities in the rules introduced by the GDPR, especially in the case of secondary use of data in international research projects. It concludes underlying the importance to develop new overall governance of personal data processing for health research in order to reduce the risk of infringements of fundamental and child' rights. The need of further safeguards and tools for the standardisation of practices is also emphasised.

I. Introduction

In recent years the interest in secondary use of clinical, pharmacological, genetic/genomic data has considerably increased, in particular for clinical research scope. Decreasing research costs, increasing patient-centred research and the speeding rate of new medical discoveries are the most evident advantages in the secondary use of personal data for research purposes.

Although offering multiple potential advantages, reuse of clinical data typically implies combining heterogeneous and multidimensional sets of data into common repositories, data warehouses, or international networks, with challenges in shared rules and meaning, in integration and interoperability.[1] Sale of clinical data remains an unresolved policy issue as well.[2] In regard to clinical data reuse for research purposes it is particularly important to address the unmet clinical needs as it is inevitably challenged both by legal and ethical considerations. This is true especially in the case of research involving vulnerable populations, such as children.

As a human being, a child must enjoy all the rights of a person, including the right to the protection of personal data. Article 16 of the UN Convention on the Rights of the Child provides that no child shall be subject to arbitrary or unlawful interference with his or her privacy, family, home or correspondence, nor to unlawful attacks on his or her honour and reputation.[3]

DOI: 10.21552/eplr/2019/4/6

* Annagrazia Altavilla, Bioethics Research Centre, University of Marseille. Jean Herveg, Head of the Liberties and Information Society (LIS) Department at CRID, University of Namur. Viviana Giannuzzi, Head of Research Department at Fondazione per la Ricerca Farmacologica Gianni Benzi ONLUS. Annalisa Landi, Researcher at Fondazione per la Ricerca Farmacologica Gianni Benzi ONLUS. Adriana Ceci, Professor, Past President of Fondazione per la Ricerca Farmacologica Gianni Benzi ONLUS. For Correspondence: <annagrazia.altavilla@univ-amu.fr>

1 Charles Safran, 'Reuse of Clinical Data' (2014) 9 Yearb Med Inform 1, 52 - 54; Khaled El Emam et al, 'Anonymising and Sharing Individual Patient Data' (2015) BMJ 350; Khaled El Emam et al, 'Anonymising and Sharing Individual Patient Data' (2015) BMJ 350.

2 Stephane Meystre et al, 'Clinical Data Reuse or Secondary Use: Current Status and Potential Future Progress' (2017) 26 Yearb Med Inform 1, 38, 52; Antoine Geissbuhler et al, 'Trustworthy Reuse of Health Data: A Transnational Perspective (2013) 82 Int J Med Inform 1, 1, 9.

3 This right is a confirmation of the general right to privacy, enshrined in Art 12 of the Universal Declaration, Art 17 of the International Covenant on civil and political rights and Art 8 of the European Convention for the Protection of Human Rights.

In the relation to personal data protection, all legal instruments have to be interpreted in the light of two fundamental principles: the best interests of the child and the evolving capacities of the child. The first principle implies both a proper appreciation of the immaturity of children and an adequate protection. The second one implies that the exercise of their rights – including those relating to data protection – must be adapted to their level of physical and psychological development. Children gradually become capable of contributing to decisions made about them. They should be consulted more regularly about the exercise of their rights, including those relating to data protection.

Taking into account their incompetence and vulnerability, children require legal representation to exercise most of their rights, including consent to data processing. However, the child's best interests can sometimes override the wishes of parents or representatives.

International norms recognise that participants have the right to withdraw from research at any time. In the context of parental broad consent however, there may be practical limitations preventing the child from exercising the right to withdraw. For instance, one purpose of broad consent is to avoid the continual re-contact of participants for each new study using their information. Thus, the right of the child to withdraw may not be executable if the child is not informed of the existence of the new study.[4] A way to overcome this issue would be to maintain contact with the child. Therefore, the data and/or samples should be coded (ie not anonymised or anonymous) in order to re-contact the child. Such re-contact is inherent (eg in paediatric longitudinal studies where the data and samples collected during the study will be kept for a long period of time). During this period, the child will grow up, mature and develop the capacity to make informed decisions. This situation raises issues with regard to the scope of parental consent, the assent of the child, the return of research results, and the confidentiality of the information collected. On this issue, it must be remembered that the rights to personal data protection belong to the child, and not to their representatives, who simply exercise them. Thus, the use of a parental broad consent would seem to deprive the child of the opportunity to exercise autonomy by not allowing his or her ratification of the parental consent at a later date.

That's why ideally the child should be kept informed during the whole duration of the research and the consent of the competent minor should be obtained in order to continue participation and/or using data and samples.

Finally, in the case of genetic research, some authors suggest limiting parental consent 'only to specific research protocols or research on certain genes or diseases' where the donor (ie the child) did not consent to the use and storage of data and/or samples.[5] According to this opinion, parental broad consent currently may not be permissible for example for genetic research involving children. Assuming that this situation limits or prevents such research taking place at all, it raises issues of equity, as many genetic diseases first manifest during childhood and paediatric genetic research is the only avenue to understanding the disease and developing treatment.[6]

In the light of these considerations, does the new GDPR (General Data Protection Regulation, GDPR)[7] integrate provisions to address the above-mentioned issues?

The European Regulation on Data Protection, entered into force in May 2018, sets up a new legal framework aimed at ensuring the protection of natural persons with regard to the processing of personal data and on the free movement of such data. This study aims at verifying if paediatric peculiarities are taken into account in the new framework and if GDPR provides adequate and clear rules to favour the secondary use of paediatric data for research purpose in international contexts. Specifically, the article analyses:

- GDPR provisions to be applied for the secondary use of personal data under the research exception and
- GDPR relevant rules for data sharing and transfer in the context of international research.

4 Bjoern Hofman, 'Broadening Consent—and Diluting Ethics?' (2009) 35 J Med Ethics 2, 125, 129.

5 Kristien Hens et al, 'Biological Sample Collections from Minors for Genetic Research: A Systematic Review of Guidelines and Position Papers' (2009) 17 European Journal of Human Genetics 8, 979, 986.

6 Annagrazia Altavilla et al, 'Report on Ethical and Governance Issues Related to Processing of Healthcare Data' GRIP Deliverable D2.04/2014.

7 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L 119/1.

The analysis is carried out in the light of the child's fundamental rights. Issues related to the lack of specific provisions covering paediatric peculiarities and rights have been identified.

II. Children's Fundamental Rights Missing Under GDPR

No reference is made in the GDPR to the UN Convention on the rights of the Child (1989) or to children's fundamental rights. Recital 38 outlines that children merit particular protection with regard to their personal data, as they may be less aware of the risks, consequences and safeguards concerned and their rights in relation to the processing of personal data. Specific protection should be applied to the use of personal data of children for the purposes of marketing or creating personality or user profiles and the collection of their personal data when using services offered directly to a child.

With respect to this, the GDPR provides specific safeguards for children in the matter of information society services as defined in the Directive EU 2015/1535[8] and underlines the fact that 'Activities addressed specifically to children shall receive specific attention' from Data Protection Authorities (Article 57 1 (b)). Nevertheless, the processing of personal data for scientific purposes must comply with other relevant legislation such as on clinical trials that include specific provisions covering children's rights and interests.[9]

III. New Definitions and Procedures Relevant For Paediatric Research

The GDPR introduces some new definitions of certain special categories of personal data, that are relevant for scientific research, such as 'Data concerning health' (Article 4 (15), Recital 28), 'Genetic data' (Article 4(13) Recital 34); 'Biometric data' (Article 4 (14)). These are marked as 'sensitive data' whose processing entails higher risks thus higher protection and stricter requirements. The processing of these data is, by principle, forbidden but exceptionally admitted for research or archiving purposes in public interest in the respect of Articles 9 and 89 of the GDPR (Article 9.2 j). No reference is made to specificities of paediatric data in these definitions, thus no specific requirements are provided for processing 'sensitive data' related to children.

Regarding the condition of the data, the GDPR confirms the previous notion of anonymous data and introduces a new definition of pseudoanonymisation as 'the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person' (eg key-coding data from electronic health records) (Article 4 (5)).[10]

Recital 26 specifies that data that could still be attributed to a natural person by the use of additional info (pseudonymised data) should be considered as personal data. To determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used (such as singling out, either by the controller or by another person) to identify the natural person directly or indirectly.

Considering the diversity in approach toward anonymization,[11] better defining this concept was particularly important[12] for improving data sharing as well as for implementing pseudonymisation as a 'standard data protection practice'[13] especially in the context of scientific research. Nevertheless, this definition seems to leave room for varying interpreta-

8 Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification) [2015] OJ L 241/1.

9 Regulation (EU) N°536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [2015] OJ L 158/1; European Commission, Ethical considerations for clinical trials on medicinal products conducted with minors, Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use (2017).

10 See also, Art 29 Data Protection Working Party (2014) Opinion 05/2014 on Anonymisation Techniques, WP 216 <https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf> accessed 20 November 2019.

11 Mark Phillips and Bartha M Knoppers, 'The Discombobulation of Deidentification' (2016) 34 Nat Biotechnol 1, 102, 103

12 Hajar Malekian, 'Pseudonymisation Under the General Data Protection Regulation: A Win-Win Approach?' (2017) 1 J Data Protect Privacy 3, 287, 293.

13 Gauthier Chassang, 'The Impact of the EU General Data Protection Regulation on Scientific Research' (2017) 11 Ecancer 709.

tion, as also recently underlined by Mourbya et al,[14] especially on how the criteria for identifiability should be determined.[15] Furthermore, the issue over third parties with access to pseudonymized data still remain unresolved.[16]

The GDPR states that Member States (MSs) may impose stricter conditions for processing 'sensitive data' but they cannot use this discretion in a way that hamper the free flow of personal data within the EU when those conditions apply to cross-border processing of such data (Recital 53). The implementation of these provisions will be particularly challenging for research projects which entail sharing of data and cross-border data processing. Moreover, it raises concerns in terms of harmonisation and inequality in the level of protection of children involved in such research. With reference to the rights of the data subjects, consent remains the cornerstone as main legal basis for the processing of personal data. Important clarifications on the characteristics of valid consent in general are introduced.

First, the informed consent to be obtained by the subject for the primary use of personal data (during a clinical trial protocol) foreseen under the Clinical Trial Regulation (CTR) 'must not be confused with the notion of consent under the GDPR, as indicated by the European Data Protection Board (EDPB).[17] Then, it must be stressed that the European Data Protection Board (EDPB) considers that the use of consent as basis for legitimise data processing in the context of clinical trials must be very carefully studied. It strongly suggests considering alternative legal basis for processing personal data for clinical trials such as the public interest (for 'ordinary' data) (or with Article 9(2)(i) or Article 9(2)(j) for health data) or the legitimate interest of the data controller (for 'ordinary' data) (or with Article 9(2)(j) for health data),[18] altogether in compliance with Article 89.

This being said and considering that explicit consent to the processing of personal data concerning health is required (Article 9), consent (under Article 6(1)(a) in combination with Article 9(2)(j)) must be given in a clear, intelligible and easily accessible form and language (Article 7). It requires an affirmative action (silence or inactivity should not constitute consent).

The subject has to be informed at least about the identity of the Controller and the purposes for which the personal data are intended (Recital 42). When data processing is carried out in pursuit of several purposes, the solution to comply with the conditions for valid consent lies in granularity, ie the separation of these purposes and obtaining consent for each purpose.[19]

In order to obtain 'informed consent' from a child, the controller must explain, in language that is clear and plain for children, how he/she intends to process the collected data (Recital 58). Reasonable efforts shall be made by the controller to verify that consent is given or authorised by the holder of parental responsibility over the child, taking into consideration available technologies (Article 8(2)).

With reference to the authorisation to be obtained by a holder of parental responsibility, the GDPR does not specify practical ways to gather the parent's consent or to establish that someone is entitled to perform this action. The Article 29 Working Party (WP29) recommends the adoption of a proportionate approach, in line with GDPR data minimisation principle (Article 8(2) Article 5(1)(c). Trusted third party verification services may offer solutions which minimise the amount of personal data the controller has to process itself.[20]

No details are provided regarding how to deal with the consent when children achieve the time of lawful capacity nor in GDPR nor in the updated WP 29 opinion on consent.[21] However, in line with Article 7(3) the WP29 specifies that, after reaching the age of digital consent, the child should have the possibil-

14 Miranda Mourbya et al, 'Are 'Pseudonymised' Data Always Personal Data? Implications of the GDPR for Administrative Data Research in the UK' (2018) 34 Computer Law & Security Review 222, 233.

15 Mahsa Shabani and Pascal Borry, 'Rules for Processing Genetic Data for Research Purposes in View of the New EU General Data Protection Regulation' (2017) 26 Eur J Hum Genet 2, 149, 156.

16 John Mark Michael Rumbold and Barbara Pierscionek, 'The Effect of the General Data Protection Regulation on Medical Research' (2017) 19 J Med Internet Res 2, e47.

17 European Data Protection Board (EDPB), Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR) (art 70.1.b) <https://edpb.europa.eu/our-work-tools/our-documents/avis-art-70/opinion-32019-concerning-questions-and-answers-interplay_en> accessed 20 November 2019.

18 ibid.

19 Article 29 Working Party, Guidelines on Consent under Regulation 2016/679 (2018) 28-29 <https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051> accessed 20 October 2019.

20 ibid.

21 ibid.

ity to withdraw the consent himself. Moreover, in accordance with the principles of fairness and accountability, the data controller should inform the child about this possibility.[22]

The concept of 'broad consent' for research purposes is recognized in the GDPR which specifies that 'if it is not possible to fully identify the purpose of data processing... at the time of data collection, ...data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research' (Recital 33). As underlined, the notion of broad consent is particularly challenging for paediatric research. Further clarification is needed in the light of the 'principle of evolving capacities of the child'.

Furthermore, it is important to point out that the term 'scientific research' is not defined in GDPR. WP 29 clarifies that in the GDPR it 'means a research project set up in accordance with relevant sector-related methodological and ethical standards, in conformity with good practice'.[23] However, especially if broadly interpreted according to Recital 159,[24] this concept raises some concerns notably regarding the potential misuse of research exemption by commercial actors. To avoid this misuse, it has been asked to elucidate a research exemption to scientific research seeking public interest.[25]

Moreover, the GDPR introduces a new obligation to undertake a Data Protection Impact Assessment (DPIA) with the aim to evaluate the likelihood and severity of the risks related to the protection of data subjects' rights and interests before carrying out data processing activities.[26] The DPIA must be used by research sponsors and investigators not only to describe and clarify how personal data will be processed and responsibly managed but also to identify the necessary enhancements and to ensure compliance while helping in determining if a prior consultation of the supervisory authority is necessary (Article 35). A DPIA is particularly important in paediatric research projects, especially in fields where the risk of violating children's rights is particularly high (eg research in rare diseases, with genetic data and/or new technologies researches).

Finally, the GDPR introduces also a new feature which consists of imposing, in some circumstances, the appointment of a Data Protection Officer (DPO)[27] who could play a central role in research projects, organisations and infrastructures. In particular, Article 37 states that the controller and the processor must designate a DPO in any case: where the processing is carried out by a public authority or a body, (except for courts acting in their judicial capacity); or where the core activities of the controller or the processor consist of processing operations which, by virtue of their nature, their scope and/or their purposes, require regular and systematic monitoring of data subjects on a large scale; or the processing includes sensitive personal data on a large scale. Indeed, the GDPR does not define the concept of 'large scale' of processing. Nevertheless, Recital 91 provides, also concerning to DPIA, that 'processing of personal data should not be considered to be on a large scale if the processing concerns personal data from patients or clients by an individual physician, other health care professional or lawyer'. Criticisms have been raised regarding this troublesome provision focused on 'specific occupation' and not on the assessment of the size of the processing 'whatever the context for ensuring appropriate protection.'[28] These criticisms are particularly relevant in the case of processing paediatric data or other sensitive data (eg genetic data, or data raised by full genome sequencing) that raises high risks in terms of privacy protection.

IV. Research Exception and Secondary Use of Personal Data

The GDPR, keeping the previous mechanisms based on a general prohibition with some important excep-

22 ibid.

23 ibid.

24 Anca Parmena Olimid et al, 'Ethical Approach to the Genetic, Biometric and Health Data Protection and Processing in the New EU General Data Protection Regulation' (2018) 59 Rom J Morphol Embryol 2 631, 636.

25 BBMRI-ERIC, 'Position Paper on General Data Protection Regulation' (2015) <http://www.bbmri-eric.eu/wp-content/uploads/BBMRI-ERIC-Position-Paper-General-Data-Protection-Regulation-October-2015_rev1_title.pdf> accessed 20 October 2019.

26 Article 29 Data Protection Working Party, 'Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is 'likely to result in a high risk' for the purposes of Regulation (2016/679)' <https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=611236> accessed 20 November 2019.

27 Article 29 Data Protection Working Party, 'Guidelines on Data Protection Officers ('DPOs') WP 243 rev.01.' <http://ec.europa.eu/information_society/newsroom/image/document/2016-51/wp243_en_40855.pdf?wb48617274=CD63BD9A> accessed 20 November 2019.

28 Chassang (n 13).

tions, specifically recognises a 'research exception' for processing special categories of personal data (such as data concerning health or genetic data) under specific conditions (considering that the EDPB makes a distinction between data processing purely related to research activities and data processing related to reliability and safety purposes).[29]

With respect to this, Article 9 al.2 (j) authorises the processing of special categories of personal data necessary for scientific research purposes. It has also been based on EU or Member State law 'which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject'.

In addition, the data controller must comply with Article 89(1) of the GDPR which requires both sufficient and adequate technical and organisational measures ensuring data protection and, in particular, the respect of data minimisation principle.

In this context, Recitals 53 and 54 stress the importance of pursuing a purpose of public interest for justifying the processing of sensitive personal data, underlying also the need that, for certain health-related purposes, the processing of such a data is carried out by persons subject to a legal obligation of professional secrecy. Furthermore, it is added that the processing of special categories of personal data necessary for reasons of public interest in the areas of public health can be carried out without consent of the data subject.

Article 89(2) specifically allows for derogations from the 'right of access by the data subject' (Article 15), 'right to rectification' (Article 16), 'right to restriction of processing' (Article 18) and 'right to object' (Article 21) in the case of the processing of personal data for scientific purposes in accordance with the legal provisions of the Article 89(1) 'in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes'. Derogations are requested by 'the fulfilment of those purposes' (Article 89(2)). It is specified that such processing of personal data without consent should be subject to suitable and specific measures so as to protect the rights and freedoms of natural persons (Recital 54). Nevertheless, it has been underlined that GDPR research exemption may enable the processing of the sensitive personal data without the data subject's consent for an undefined period of time for research purposes,[30] especially in the case of particularly sensitive data (eg genetic data).

Regarding the possibility to use clinical trial personal data outside the clinical trial protocol for scientific purposes, it must be repeated that the consent required by the CTR is not the same as the consent used in the GDPR as a legal basis to process personal data.[31]

The EPDB contends that the compatibility test (Article 5(1)(b)) should not be excluded, subject to the conditions set forth in Article 89, for the secondary use of clinical personal data outside the clinical trial protocol for other scientific purposes. However, these processing activities must comply with all other relevant applicable data protection principles (ie fairness, lawfulness, necessity, proportionality, as well as data quality). Thus, research exemption provisions could provide a legal basis for the 'secondary processing' of data based on a presumption of compatibility.

According to Article 5 and Recital 50, the 'processing of personal data for purposes other than those for which the personal data were initially collected should only be allowed where the new purpose of the processing is compatible with the purposes for which the personal data were initially collected', where Article 89 (1) requiring for safeguards is respected.

This presumption of compatibility with the initial purpose of the processing is linked to the specific exemption to the principle of storage minimisation, where the further processing (eg storage) is for research or archiving purposes in the public interest (Article 5(1)(e).

Nevertheless, this presumed compatibility is not fully automatic and must answer to several requirements such as the respect of the 'data minimization', in pursuance of the proportionality and necessity principles (Article 5 c)). This further processing is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing da-

29 EPDB, 'Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection Regulation (GDPR) (art 70.1.b)' <https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_opinionctrq_a_final_en.pdf> accessed 20 November 2019.

30 Kärt Pormeister, 'Genetic Data and the Research Exemption: Is the GDPR Going Too Far?' (2017) 7 International Data Privacy Law 2 137, 146.

31 EPDB (n 29).

ta which do not permit or no longer permit the identification of data subjects (eg pseudonymisation of the data), and provided that appropriate safeguards exist (eg secured and separated storage of the identifiers - codes) (Article 89 (1) and Recital 156).

Furthermore, where the processing for another purpose is not based on the data subject's unambiguous consent or on an EU or Member States law, the data controller shall perform a compatibility test based on elements enumerated in the GDPR (Article 6(4) and Recital 50). Where the results of the test show that the further processing remains fair or otherwise licit, the compatibility test is satisfied, and no legal basis other than the one allowing the initial processing of the personal data is required. If not, the further processing will have to rely on a separate legal basis (eg re-consent of the individual).

Finally, Article 6 lays out the grounds for the lawful processing of personal data without consent, including but not limited to the condition when 'processing is necessary for the purposes of the legitimate interests'. Although processing for research purposes is not explicitly listed under 'legitimate interests', explanations provided in Recitals 47 and 113 could be considered for potentially providing sufficient grounds to process personal data for research purposes without consent. Of course, Article 89 of the GDPR still applies. Nevertheless, it has to be considered that this exception cannot be applied where 'such legitimate interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data'. Clarifications related to the applicability of this 'consent exception' in paediatric research are needed. Specific and adequate conditions should be identified taking into account children's fundamental rights and interests.

V. Data Sharing and Transfer Outside the EU

According to the GDPR, a transfer of personal data to a third country organisation may take place only if the level of protection of natural persons ensured in the EU is not be undermined. To this aim, many instruments have been provided. The most relevant instruments used in the context of research are the 'adequacy decisions', the 'Code of conduct' and the 'data subject consent'.

Since the approval of the Data Protection Directive in 1995, adequacy has been the cornerstone of EU data protection justifications for transfer. It is based on the principle that a third country or an international organisation ensures an adequate level of protection that implies prior adequacy decisions taken by the European Commission.[32]

After the Schrems case,[33] that invalidated a prior adequacy decision linked to the United States/EU Safe Harbour Framework, and the recent Edward Snowden's revelations about mass state surveillance by US government agencies and their counterparts within the other countries, the EU deemed particularly important the very notion of security and protection of human beings as well as the conception that we have of freedom and fundamental rights.[34] This position has been recently renewed after the Cambridge Analytica revelations.[35]

Every four years the Commission has to analyse the application and functioning of adequacy decisions.

In the lack of any 'adequacy decision', a Code of Conduct may be used as an independent justification allowing the transfer of personal data. The role of such a Code is not to set aside the GDPR's obligations but only to clarify and assist in interpreting them in a specific context. To this aim it should be approved by the European Commission, according to the processes set out in the Regulation 2016/679 (GDPR Article 40) and paired with binding and enforceable commitments to apply appropriate safeguards, 'including as regards data subject's rights' (Article 46).

It is important to underline that 'although adherence with an approved code of conduct provides evidence of compliance with the GDPR generally, it does

32 Mark Phillips, 'International Data-Sharing Norms: From the OECD to the General Data Protection Regulation (GDPR)' (2018) 137 Human Genetics 575, 582.

33 Case C-362/14 *Schrems v Data Protection Commissioner* [2015] ECLI:EU:C:2015:650.

34 European Parliament, 'The US Surveillance Programmes and Their Impact on EU Citizens' Fundamental Rights' Note PE 474.405 (2013) <http://www.europarl.europa.eu/meetdocs/2009_2014/documents/libe/dv/briefingnote_/briefingnote_en.pdf> accessed 20 January 2019.

35 Hillary Osborne and Hannah Jane Parkinson, 'Cambridge Analytica Scandal: The Biggest Revelations So Far' *The Guardian* (London 22 March 2018) <https://www.theguardian.com/uk-news/2018/mar/22/cambridge-analytica-scandal-the-biggest-revelations-so-far> accessed 20 January 2019.

not provide proof of compliance.'[36] This means that, even assuming perfect adherence to an approved Code of Conduct, 'it remains theoretically possible to be found to have violated the GDPR'.[37] Nevertheless, a code of conduct especially devoted to health research could help to clarify and specify certain rules of the GDPR 'providing practical certainty in the form of guidance.'[38]

The BBMRI-ERIC is leading the coordination of a code of conduct for health research.[39] The aim is to help demonstrate compliance by controllers and processors with the regulation and foster transparency and trust in the use of personal data in the area of health research. Thus, it should be important for stakeholders working in the paediatrics sector to take part in the consultation process in order to ensure that paediatric peculiarities are considered. A code of conduct addressing paediatric peculiarities may be a useful tool to facilitate international paediatric research projects including data sharing practices.

Another important legal basis for authorising the transfer of personal data is the consent of the data subject. Until now it has been the most attractive way used for transferring personal data within international health research projects. It allowed the avoidance of uncertainties linked to other measures, such as the adequacy decisions, difficult to be applied in research consortia which include constantly new partners not always based in countries with an appropriate level of data protection. Furthermore, within biomedical research, for researchers it is quite easy to extend the consent obtained for participating in research to cover also international transfer of the participants' data.

With reference to the consent, GDPR provides that, in the absence of an adequacy decision (Article 45(3)) or of appropriate safeguards (Article 46), 'the data subject has explicitly consented to the proposed transfer, after having been informed of the possible risks of such transfers for the data subject...' (Article 49,1 –a). Furthermore, it is required that where the data subject is physically or legally incapable of giving consent, the transfer may take place only if it is necessary in order to protect the vital interests of the data subject or of other persons (Article 49,1 –f).

Thus, under the GDPR, consent for transfer, especially related to paediatric data, is likely to be interpreted narrowly. Furthermore, applying the 'flexible approach' of Recital 33, introducing the 'Broad consent', it will be subject to stricter interpretation and may require a high degree of scrutiny[40] especially in the case of special categories of data (sensitive data). Alternative safeguards should be established when broad consent is paired with international transfer, notably when the consent derogation is used as legal basis to justify transfer where the processor is also relying on broad consent to personal data processing.[41]

These additional safeguards (eg data minimisation, anonymisation, data security, transparency) should be applied to offset the absence of 'specific consent'. In accordance to the principle of transparency, Article 29 WP specifies that a research plan, available for data subjects before they consent, should be set up. A specific person that participants can contact for their questions over time should be designated[42] to guarantee that the consent is really 'informed'. Finally, implementing these additional safeguards should be particularly useful in the paediatric context considering ethical and legal issues raised by the respect of the principle of the autonomy and the evolving capacities of the child.

VI. Discussion and Conclusions

The GDPR enables a new legal framework for data protection and processing that is also relevant for scientific research. It provides legal basis for processing personal data as well as for secondary use of these data for research purposes. Nevertheless, the GDPR does not contain adequate provisions to ensure children rights especially in the context of scientific research.

All the new definitions adopted in the GDPR represent a very useful and workable basis to foster research, but some issues might be triggered regarding

36 Mark Phillips, 'International Data-Sharing Norms: From the OECD to the General Data Protection Regulation (GDPR)' (2018) 137 Human Genetics 575, 582.

37 ibid.

38 ibid.

39 A Code of Conduct for Health Research <http://code-of-conduct-for-health-research.eu> accessed December 20 2018; J-E Litton, 'We Must Urgently Clarify Data-Sharing Rules' (2017) 541 Nature 7638, 437.

40 Article 29 Working Party, 'Guidelines on consent under Regulation 2016/679' (2018) <https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051> accessed 20 December 2018;

41 Khaled El Emam et al (n 1).

42 Article 29 Working Party (n 40).

the boundaries of theses notions[43], especially within the 'research exception'.

Both private and publicly funded research could benefit from the research exemption provisions under the GDPR. However, to face possible concerns regarding potential misuse of research exemption by commercial actors, the need for the alignment of the research's objectives with the public interests has been underlined. More transparency should be applied in the procedure of data processing to foster the advancement of biomedical research.[44]

In accordance with the GDPR, using data for research purposes and sharing them for secondary uses require adopting further organizational safeguards. An on-going level of control on these secondary uses for research purposes should be provided. Since the new Regulation does not provide with details about these safeguards, Member States will be in charge to elaborate conditions and safeguards. This could raise some concerns in terms of harmonisation and increase the competition amongst Member States, which could lead to the adoption of less protective rules with the aim to favour processing of data on a national level. This could result in some inequalities in the protection level of children's fundamental rights across Europe, in spite of the principle of equality of treatment that is an implicit milestone in building a European wide-democratic society.

The use of 'broad consent' as a legal basis for processing personal and sensitive data in paediatric research and for data sharing and transfer, notably at international level, should be clarified. In the implementation of GDPR, it should be specified how the respect of children's autonomy and fundamental rights will be guaranteed.

In the light of the ethical and legal concerns associated with secondary use of personal data for research under the GDPR, codes of conduct are an interesting tool for paediatric research communities looking for more standardisation of their data protection practices.

Beyond legal requirements, an overall governance of personal data processing for health research should be developed and should be aimed at addressing ethical and legal issues of secondary use of personal paediatric data in research projects and consortia. These issues should be treated as 'moving targets'[45] to face risks associated with emerging technologies, such as the risk of discrimination based on personal/sensitive/health data in the long term. This risk is relevant for children, especially in case of particular vulnerability (eg children with rare diseases).

In line with the WP 29 Report,[46] specific, competent and independent oversight bodies[47] with adequate and pluri-disciplinary expertise should be set up. These bodies shall include representatives of all the main stakeholders (including patients' representatives).

Finally, within a global governance of research consortia, the DPIA (Article 35 GDPR) represents an important self-assessment exercise to avoid high risks related to the protection of the rights and freedoms of natural persons, especially if vulnerable persons such as children. This could be particularly relevant where special categories of data is processed on large scale (eg research cohort) or where new technologies are used (eg genome sequencing).[48] This could be also the case where are used some e-health technologies based on automated processing with a systematic and extensive evaluation of personal aspects, allowing legal binding decision for the person concerned, are used. Moreover, the DPIA results represent an opportunity for standardising data protection practices in paediatric research and are an important tool to avoid the risk of infringements of children's rights.

43 Chassang (n 13).

44 Shabani and Borry (n 15).

45 ibid.

46 Article 29 Working Party (n 40).

47 Nuffield Council on Bioethics, 'The Linking and Use of Biological and Health Data' (2013) <https://nuffieldbioethics.org/wp-content/uploads/Biological_and_health_data_web.pdf> accessed 20 November 2019.

48 Chassang (n 13).